CLAIMS

1. A method of predicting the risk of pre-eclampsia in a pregnant woman, the method comprising the steps of:

(a) obtaining a sample of blood from the woman;

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(b) subsequently assaying the sample for the levels of free β-human chorionic gonadotrophin (free β-hCG) and Inhibin A present in the sample; and

(c) determining the risk of pre-eclampsia using the measure levels of free β-human chorionic gonadotrophin (free β-hCG) and Inhibin A present in the sample.

2. A method as claimed in claim 1 which further comprises assaying the sample for the levels of unconjugated oestriol (uE_3).

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3. A method as claimed in claim 1 or claim 2 in which the method is carried out after 20 weeks of pregnancy,

4. A method as claimed in claim 3 in which the method is carried out at the end of the second trimester and the beginning of the third trimester.

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5. A method as claimed in any one of claims 1 to 4 in which the determination of risk in step (c), is undertaken by comparing the levels of free β-human chorionic gonadotrophin (free β-hCG) and Inhibin A present in the sample with those in a control sample.

6. A method as claimed in claim 5, in which the determination of risk comprises deriving the likelihood ratio using a multivariate analysis based on distribution parameters from a set of reference data.

7. A method as claimed in claim 6, in which the multivariate analysis is a multivariate Gaussian analysis.

8. A method as claimed in 7, in which the estimation of risk consists of multiplying the likelihood ratio by the background risk for pre-eclampsia.

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9. A method as claimed in any one of claims 1 to 8, the method further comprising a step (d) of re-expressing each measured screening marker level as a multiple of the median level of the respective screening marker in unaffected pregnancies of the same gestational age as the fetus of the pregnant woman.

10. A method as claimed in claim 9, in which the screening marker levels are adjusted to allow for one or more factors selected from the group of maternal race, maternal weight, multiple birth and diabetic status.

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11. An apparatus for determining whether a pregnant woman is at an increased risk of pre-eclampsia, the apparatus comprising:

(a) data input means for inputting a measurement of the serum levels of Inhibin A and free β-human chorionic gonadotrophin (free β-hCG) in a sample obtained from said pregnant woman; and

(b) calculation means for determining the risk of pre-eclampsia using the input levels of the serum markers Inhibin A and free β-human

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chorionic gonadotrophin (free β-hCG).

12. An apparatus as claimed in claim 11, in which the data input means (a) further comprises a data input means for inputting a measurement of the serum levels of unconjugated oestriol (uE_3) in a sample obtained from the pregnant woman.

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13. An apparatus as claimed in claim 11 or claim 12, in which the calculation means is arranged to determine the risk of pre-eclampsia by deriving the likelihood ratio for pre-eclampsia using a multivariate analysis based on distribution parameters derived from a set of reference data.

14. An apparatus as claimed in claim 13, in which the multivariate analysis is a multivariate Gaussian analysis.

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15. An apparatus as claimed in any one of claims 11 to 14, in which the apparatus further comprises (c) means for re-expressing the levels of each input screening marker as a multiple of the median level of the respective screening marker in unaffected pregnancies of the same gestational age as the fetus of the pregnant women and supplying the re-expressed screening marker levels to said calculation means.

SUB B13

16. A kit for predicting the onset of pre-eclampsia in a pregnant woman, comprising means for assaying a sample from the women for the levels of free β-human chorionic gonadotrophin (free β-hCG) and Inhibin A present in the sample.

17. A kit as claimed in claim 16 which further comprises a means for assaying the sample for the levels of unconjugated oestriol (uE_3).